UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX

FILED 30 JULY 2021 U.S. EPA - REGION IX

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IN THE MATTER OF:) U. S. EPA Docket No.	•
) RCRA-09-2021-0061	
Minaris Regenerative Medicine, LLC EPA ID. No. CAL000431599 Respondent.) EXPEDITED SETTLEMENT) AGREEMENT AND) FINAL ORDER)	
)	

EXPEDITED SETTLEMENT AGREEMENT

- 1. The U.S. Environmental Protection Agency ("EPA") alleges that Minaris Regenerative Medicine, LLC ("Respondent"), owner or operator of the facility located at 291 N. Bernardo Avenue, Mountain View, CA 94043 (the "Facility"), failed to comply with the Biennial Reporting and EPA identification number requirements under the Resource Conservation and Recovery Act ("RCRA") and the EPA approved and authorized California hazardous waste management program¹.
- 2. Under 22 CCR § 66262.41 [40 Code of Federal Regulations ("CFR") § 262.41], Respondent was required to submit a 2019 Biennial Report by March 1, 2020.
- 3. Under 22 CCR § 66262.12(a) [40 CFR § 262.18(a)], Respondent is required to obtain an EPA identification number to ship regulated quantities of RCRA hazardous waste.
- 4. EPA and Respondent agree that settlement of this matter for a penalty of Three Thousand Five Hundred Dollars (\$3,500) is in the public interest.
- 5. EPA is authorized to enter into this Expedited Settlement Agreement ("Agreement") pursuant to Section 3008 of RCRA and 40 C.F.R. § 22.13(b).
- 6. In accordance with 40 C.F.R. § 22.18(b)(2) and for the purpose of this proceeding, Respondent: (i) admits that EPA has jurisdiction over the subject matter of this Agreement and over Respondent; (ii) neither admits nor denies the specific factual allegations contained in the Agreement; (iii) consents to any and all conditions specified in this Agreement and to the assessment of the civil administrative penalty specified in this Agreement; (iv) waives any right to contest the allegations contained in this Agreement; and (v) waives the right to appeal this Agreement as a final order.
- 7. By its signature below Respondent certifies, subject to civil and criminal penalties for

¹ All citations in this Agreement refer to the California Code of Regulations ("CCR") refer to Division 4.5 of Title 22 of the current California Code of Regulations. EPA is enforcing California hazardous waste management program requirements as approved and authorized by the United States on August 1, 1992 (see 57 Fed. Reg. 32726, July 23, 1992), September 26, 2001 (66 Fed. Reg. 49118, September 26, 2001), October 7, 2011 (see 76 Fed. Reg. 62303, October 7, 2011) and January 14, 2020 (see 85 Fed. Reg. 2038, January 14, 2020). Corresponding Federal citations are provided as a convenience in brackets.

making a false submission to the United States Government, that: (1) the alleged violation has been corrected, and (2) Respondent is submitting proof of payment of the civil penalty with this Agreement. The civil penalty of Three Thousand Five Hundred Dollars (\$3,500) should be paid in accordance with EPA Region IX Penalty Collection Procedures provided to the Respondent.

- 8. Upon the effective date of this Agreement, payment of the civil penalty shall constitute full settlement of the civil claim alleged herein.
- 9. EPA reserves all of its rights to take enforcement action for any other past, present, or future violations by Respondent of RCRA, any other federal statute or regulation, or this Agreement.
- 10. Upon signing and returning this Agreement to EPA, Respondent waives the opportunity for a hearing or appeal pursuant to Section 3008(b) of RCRA.
- 11. Each party shall bear its own costs and fees, if any.
- 12. This Agreement is binding on the parties signing below, and in accordance with 40 CFR § 22.31(b), is effective upon filing.

Date 07/08/2021

IT IS SO AGREED,

Name (print): Jesus Augula

Title (print): Sr. Site Viruetor

Signature: Signature:

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APPROVED BY EPA:

AMY MILLER-Digitally signed by AMY MILLER-BOWEN **BOWEN**

Date: 2021.07.15 15:28:37 -07'00'

Date: ____

Amy C. Miller-Bowen, Director Enforcement and Compliance Assurance Division U.S. EPA Region IX

IT IS SO ORDERED:

STEVEN JAWGIEL Digitally signed by STEVEN JAWGIEL

Date: 2021.07.30 12:44:00 -07'00'

Steven L. Jawgiel Regional Judicial Officer U.S. EPA Region IX

CERTIFICATE OF SERVICE

This is to certify that the fully executed Expedited Settlement Agreement in the matter of Minaris Regeneration Medicine, LLC (RCRA-09-2021-0061) was filed with the Regional Hearing Clerk, U.S. EPA, Region 09, and that a true and correct copy of the same was sent to the following parties:

FOR REPSONDENT: **VIA E-MAIL**

Stephen Humes

Holland & Knight, LLP 31 West 52nd Street New York, NY 10019 Steve.Humes@hklaw.com

FOR COMPLAINANT: **VIA E-MAIL**

Andrew Helmlinger

Assistant Regional Counsel U. S. EPA – Region 9 San Francisco, CA 94105 Helmlinger.Andrew@epa.gov

Armsey, Digitally signed Armsey, Steven Date: 2021.07.30

Digitally signed by Date: 2021.07.30 18:36:52 -07'00'

Steven Armsey Regional Hearing Clerk U.S. EPA, Region IX

Date